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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TEVA BRANDED
PHARMACEUTICAL PRODUCTS
R&D, INC., NORTON (WATERFORD)
LTD., and TEVA
PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC, AMNEAL
IRELAND LIMITED, AMNEAL
PHARMACEUTICALS LLC, and
AMNEAL PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 23-cv-20964-SRC-
MAH

Electronically Filed

PLAINTIFFS' RESPONSIVE CLAIM CONSTRUCTION BRIEF

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GLOSSARY OF TERMS

Term	Description
The '289 Patent	U.S. Patent No. 9,463,289 (Pl. Ex. 1) ¹
The '587 Patent	U.S. Patent No. 9,808,587 (Pl. Ex. 2)
The '808 Patent	U.S. Patent No. 10,561,808 (Pl. Ex. 3)
The '889 Patent	U.S. Patent No. 11,395,889 (Pl. Ex. 4)
The Asserted Claims	Claims 1, 2, and 4–8 of the '289 patent; claims 1, 2, 4–8, 11, and 12 of the '587 patent; claims 1 and 27–29 of the '808 patent; and claims 1–4 and 6 of the '889 patent
The Asserted Patents	The '289, '587, '808, and '889 patents
Inhaler Terms	<p><u>Term 1</u>: “An inhaler for metered dose inhalation” ('289 patent, claim 1; '587 patent, claims 1, 12)²</p> <p><u>Term 4</u>: “an inhaler” ('808 patent, claim 1)</p> <p><u>Term 6</u>: “a metered dose inhaler” ('889 patent, claim 1)</p>
Canister Terms	<p><u>Term 2</u>: “medicament canister” ('289 patent, claims 1, 2; '587 patent, claims 1, 2, 12)</p> <p><u>Term 7</u>: “canister” ('889 patent, claim 1)</p>

¹ “Pl. Ex. __” refers to the numbered exhibits submitted with Plaintiffs’ Opening Claim Construction Brief (D.E. 116) (“Teva Br.”) and this brief. “Def. Ex. __” refers to the numbered exhibits submitted with Defendants’ Opening Claim Construction Brief (D.E. 117) (“Def. Br.”).

² The term number refers to the number assigned to the disputed constructions provided in the Joint Claim Construction and Prehearing Statement (“JCCS”). *See* D.E. 111-1 at 6-8.

Term	Description
Dose Counter Terms	<u>Term 3</u> : “A dose counter for an inhaler” (’808 patent, claim 1) <u>Term 5</u> : “An incremental dose counter for a metered dose inhaler” (’889 patent, claim 1)
Defendants	Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc.
Teva	Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.

I. INTRODUCTION

Each of the Asserted Claims recites an “inhaler” and a “dose counter.” The Asserted Patents describe the inventions as an “inhaler” with a “dose counter.” During prosecution, the applicant, examiner, and Patent Trial and Appeal Board described the inventions as comprising an “inhaler” with a “dose counter.” Despite those repeated express references to an inhaler with a dose counter, Defendants argue that the claims are *not* limited to an inhaler, but instead require only the various specific structures called out in the bodies of the claims—no matter whether those structures are incorporated into an inhaler, an injector pen, any other structure, or indeed, no additional structure at all. That effort is flatly inconsistent with the intrinsic record, which makes clear that the references to an “inhaler” and a “dose counter” for an inhaler provide essential structure and are necessary to give life, meaning, and vitality to the claims. The claims are limited to inhalers with a dose counter, and the Court should construe them in accordance with the claim language, specification, and prosecution history.

Defendants’ fallback argument, that the claims should be construed not to require an active drug, is equally meritless. Even though the purpose of the dose counter is to accurately count the remaining doses of the active drug that are contained within the inhaler, Defendants argue the claims do not require the inhaler to contain any drug whatsoever. To Defendants, a “dose counter” need not count

doses of an active drug, and a “medicament canister” need never contain any medicament. That position is precisely the kind of attempt to construe individual claim terms by divorcing them from their context that Federal Circuit precedent forbids; it ignores the common meaning of the claims and the intrinsic record, and it, too, should be rejected. Instead, the Court should construe the Asserted Claims to require an inhaler containing an active drug capable of being dispensed via the inhaler to the lungs.

II. ARGUMENT

A. The Inhaler Terms are limiting, and Teva’s proposed constructions should be adopted

Each Asserted Claim explicitly requires an “inhaler.” Defendants’ arguments to avoid the import of this limitation—that the preambles are not limiting or that the term does not require the presence of a drug—should be rejected. For ease of reference, Teva will group the terms as Defendants have done in their Opening Brief. The disputed Inhaler Terms (with the numbering from the JCCS) are as follows:

- Term 1: “***An inhaler for metered dose inhalation***, the inhaler comprising” (’289 patent, claim 1 and ’587 patent, claims 1 and 12)
- Term 4: “A dose counter for ***an inhaler***, the dose counter having” (’808 patent, claim 1)
- Term 6: “An incremental dose counter for ***a metered dose inhaler*** having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having” (’889 patent, claim 1)

For each term, the preamble is limiting and the Inhaler Term is an inhaler “containing

an active drug capable of being dispensed via the inhaler to the lungs.”

1. The disputed phrases in the preamble are limiting

As explained in Teva’s Opening Brief, the preambles of the Inhaler Terms are limiting for multiple, independent reasons. Each of the three arguments Defendants raise for why the preambles of the Inhaler Terms are not limiting are wrong as applied to the claims here.

First, Defendants argue—in passing in a single paragraph—that these preambles do not provide “essential structure” for the bodies of the claims and are not “necessary to give life, meaning, and vitality” to the claims. Def. Br. at 6 (quoting *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002)). The parties agree that “[a claim] preamble is generally construed to be limiting if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim.” *Proveris Sci. Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372 (Fed. Cir. 2014) (quotation marks and citation omitted). The disagreement is whether these standards are met. As explained in Teva’s Opening Brief, the disputed preambles provide essential structure and meaning for the bodies of their respective claims. *See* Teva Br. at 10-13 (Inhaler Term 1); *id.* at 25-27 (Inhaler Term 4); *id.* at 33-34 (Inhaler Term 6). The body of each independent claim of the Asserted Patents does not recite the complete structure of an inhaler. To the contrary, if one ignored the inhaler language, the structure recited in the body of the

claims would be incomplete. *See Lemoine v. Mossberg Corp.*, No. 2020-2140, 2021 WL 4199934, at *2 (Fed. Cir. Sept. 15, 2021) (affirming district court’s determination finding preamble limiting, in part, “because it provides important context for the nature and structure of the invention being claimed, and that without the context provided by the preamble it is difficult to make sense of the claims”); *Rowe v. Dror*, 112 F.3d 473, 478-79 (Fed. Cir. 1997) (finding phrase in the claim preamble limiting because it provided “structural limitations” for the claimed invention). Indeed, if the preambles were not limiting, then these independent claims would require some (but not all) parts of an inhaler—e.g., “a medicament canister,” “a dose counter,” etc.—but not a complete inhaler or the inhaler itself. *See, e.g.*, ’289 patent, claim 1. The same is true for the dependent claims. If these independent claims did not require the inhaler itself, the dependent claims would require some parts of an inhaler without the corresponding structure of the inhaler. *See, e.g.*, ’289 patent, claim 2 (“The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.”).

Second, Defendants’ argument that the preambles for the Inhaler Terms are not necessary to provide antecedent basis to the claim bodies is misplaced and incorrect. Def. Br. at 6-8. As an initial matter, antecedent basis is not required for a preamble phrase to be found limiting. *Catalina*, 289 F.3d at 808-09. Moreover, as explained in Teva’s Opening Brief and below, the preambles of the Inhaler Terms

for the '289 and '587 patents provide antecedent basis for terms in the bodies of the claims. *See* Teva Br. at 13-14. In their Opening Brief, Defendants quote the entirety of claim 1 of three of the patents in dispute (the '289 patent; the '808 patent; and the '889 patent) to attempt to show the lack of antecedent basis. Def. Br. at 7-8. Notably absent is a recitation of claim 1 of the '587 patent. Defendants argue that the claims of that patent do not contain the phrase “an inhaler for metered dose inhalation” in the body of the claims, Def. Br. at 7, but ignore that claim 1 of the '587 patent explicitly relies on the inhaler limitation for antecedent basis, having a limitation to “the inhaler” at the end of the claim:

1. ***An inhaler for metered dose inhalation***, the inhaler comprising:
 - a main body having a canister housing,
 - a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
 - a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
 - wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
 - wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
 - wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner

wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.³

As explained in Teva’s Opening Brief (at pp. 13-14), this antecedent basis requires interpreting the preamble as limiting. *See Catalina*, 289 F.3d at 808; *ABS Glob., Inc. v. Cytonome/St, LLC*, 84 F.4th 1034, 1040 (Fed. Cir. 2023). Defendants cite no authority for the notion that a claim must repeat the entirety of a phrase to provide antecedent basis—which is not the law. *See, e.g., Bell Commc’ns Rsch., Inc. v. Vitalink Commc’ns Corp.*, 55 F.3d 615, 621 (Fed. Cir. 1995) (“said packet” referred back to preamble phrase “said packet including a source address and a destination address”).

The parties’ agreed-upon constructions in the JCCS further prove the point. The parties have agreed on the constructions of three separate claim terms for the ’289 and ’587 patents that each refer to “the inhaler body.” To resolve potential disputes over the interpretation of the terms “canister housing,” “main surface of the inner wall,” and “inner wall” in the ’289 and ’587 patents, the parties have agreed upon constructions that explicitly reference “the inhaler body.” D.E. 111-1 (JCCS) at 3-4. The reference to “the inhaler” in these agreed-upon constructions of claim

³ Claim 1 of the ’587 patent includes nearly the same language as claim 1 of the ’289 patent, and with the addition of the final clause “such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

terms in the bodies of the respective independent and dependent claims is a reference to the preamble phrase “[a]n inhaler for metered dose inhalation” found in the preambles of independent claim 1 of the ’289 patent and independent claims 1 and 12 of the ’587 patent. If Defendants were correct, and the preamble was not limiting, the claims would not be limited to an inhaler and references to “the inhaler” in the construction of these other terms would make no sense. The use of the definite article “the” in this context explicitly refers back to a previously-claimed limitation. *ABS Glob.*, 84 F.4th at 1040 (“The use of the definite article, ‘the,’ means that the phrase ‘the sample stream’ refers back to earlier language as an antecedent. The antecedent language is ‘a sample stream’ in the preceding limitation”). Accordingly, the disputed preamble phrases of the Inhaler Terms provide antecedent basis for claim terms found in the bodies of both independent and dependent claims.⁴

Third, Defendants overlook the patentable significance of the Inhaler Terms emphasized in the specification and prosecution history of the Asserted Patents. Def. Br. at 8-9. The purpose of the invention is to provide an accurate dose counter for an inhaler. To ignore that context, and construe the claims that explicitly recite an inhaler to not be limited to an inhaler makes no sense. The shared specification of

⁴ The references to “the inhaler body” for these agreed-upon constructions also establish “the important context” provided by the preamble. *Lemoine*, 2021 WL 4199934, at *2. As noted above, because the preambles are “essential to understand . . . terms in the claim body,” they are limiting. *Catalina*, 289 F.3d at 808.

the Asserted Patents explains that “[t]he present invention aims to alleviate at least to a certain extent one or more of the problems of the prior art.” ’289 patent at 2:36-37.⁵ While Defendants are correct that the specification recognizes that “[i]nhalers incorporating dose counters have . . . become known,” Defendants ignore the problems identified for these prior art inhalers incorporating dose counters in the same section. Def. Br. at 8 (quoting ’289 patent at 1:55-56). These are problems which the claimed inventions helped solve. For instance, the specification explains that “some dose counters do not keep a particularly reliable count, such as if they are dropped onto a hard surface” and that “dosing becomes unreliable,” which is “potentially hazardous for the user.” ’289 patent at 1:52-54, 2:6-8. The Asserted Patents addressed these problems by, *inter alia*, “improv[ing] dose counters further and, in particular, . . . provid[ing] extremely accurate dose counters for manually-operated canister-type metered dose inhalers.” *Id.* at 2:9-12. The specification thus evidences the patentable significance of the Inhaler Terms—the very premise of the claimed inventions is accurately counting the doses of the drug in *the inhaler*. See *Catalina*, 289 F.3d at 809 (“[P]reamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear

⁵ As noted in Teva’s Opening Brief, each of the four Asserted Patents share the same specification. Citations to the common specifications of these patents refer to the ’289 patent. Unless otherwise noted, identical disclosures appear in the other Asserted Patents.

reliance on those benefits or features as patentably significant.”).

The prosecution history further establishes that the preambles for the Inhaler Terms are limiting. In response to a Final Office Action, Teva distinguished the claimed invention over the examiner’s rejection by emphasizing how the claimed inhaler is functionally better than the examiner’s suggestion because the examiner’s suggestion “would increase the airflow resistance of the inhaler and could affect the ability of users with reduced lung function . . . to draw air through the inhaler and inhale medicament effectively.” Pl. Ex. 8 (File History, U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.) at 6-7. Similarly, during an appeal of the examiner’s rejection during the prosecution of the ’808 patent, Teva distinguished the claimed invention over the prior art by, *inter alia*, explaining how the claimed invention “prevents undesirable movement of the counter display if the inhaler is dropped.” Pl. Ex. 15 (File History, U.S. Patent App. No. 15/262,818, May 21, 2018 Appellant’s Brief) at 3, 7. In reversing the examiner’s rejection, and allowing the ’808 patent to issue, the Patent Trial and Appeal Board acknowledged that the applicant “describes the invention as relating to a metered dose inhaler” and that “the invention seeks to count how many doses of any inhaler have been used while not counting doses where the inhaler canister does not fire.” Pl. Ex. 16 (File History, U.S. Patent App. No. 15/262,818, Sep. 20, 2019 Patent Board Decision) at 2; *see* Pl. Ex. 17 (File History, U.S. Patent App. No. 15/262,818, Oct. 2, 2019 Notice of

Allowance) at 2. Teva relied on the features and benefits of the “inhaler” in the preamble as patentably significant to distinguish the examiner’s grounds for rejection. The prosecution history therefore provides an additional basis for why the preambles are limiting. *Catalina*, 289 F.3d at 808. For all of these reasons, the Court should reject Defendants’ argument and construe the Inhaler Terms as limiting.

2. The Inhaler Terms should be construed as containing an active drug for inhalation into the lungs

As for the proper construction of the Inhaler Terms, the parties dispute whether an inhaler contains an active drug. Consistent with the intrinsic and extrinsic record, Teva’s proposed constructions for the Inhaler Terms require that the claimed inhaler “contain[] an active drug capable of being dispensed via the inhaler to the lungs.” Defendants’ proposal consists entirely of adding the word “device” to the disputed term based on references to inhalers referred to as a “device” in the specification and prosecution history. Defendants’ proposal, however, is based on the flawed conclusion that references to an inhaler as a device mean the Inhaler Terms need not contain an active drug. That conclusion does not follow from that premise. As explained more below, the Inhaler Terms should not be construed to include an empty device as Defendants argue.

Defendants ignore the claims in arguing for the proper construction of the Inhaler Terms. Def. Br. at 9-12. “[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms” and “the context in which a

term is used in the asserted claim can be highly instructive.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). As explained in Teva’s Opening Brief, this is true for the claims containing the Inhaler Terms. *See* Teva Br. at pp. 16-17 (Inhaler Term 1); *id.* at 29-30 (Inhale Term 4); *id.* at 36-37 (Inhaler Term 6). By way of example, each of the claims containing the Inhaler Terms recite a “dose counter”—a dose counter that counts the doses of the active drug that remain in the inhaler. Additionally, the relevant claims of the ’289 and ’587 patents recite a “medicament canister,” which is part of the inhaler and contains a “medicament” or active drug.

Casting aside *Phillips*’ requirement to consider the claims themselves, Defendants skip the claims and solely examine the specification and prosecution history. *Phillips*, 415 F.3d at 1314. But even the cited portions of the specification do not support Defendants’ position. Defendants provide a series of block quotes from the specification that they argue demonstrate that “the specification repeatedly refers to inhalers as ‘devices.’” Def. Br. at 9-10. What Defendants ignore is that these same citations support that the inhaler contains an active drug:

“The dose counter must not count a dose when the canister has not fired since this might wrongly indicate to the user that a dose has been applied and if done repeatedly the user would throw away the canister or whole device before it is really time to change the device due to the **active drug** and propellant reaching a set minimum.” (’289 patent at 2:20-25 (emphasis added).)

“Additionally, the canister must not fire without the dose counter counting because the user may then apply another dose thinking that the canister has not fired, and if this is done repeatedly the **active drug** and/or propellant may run out while the user thinks the device is still suitable for use according to the counter.” (’289 patent at 2:25-31 (emphasis added).)

“A drawback of self-administration from an inhaler is that it is difficult to determine how much **active drug** and/or propellant are left in the inhaler, if any, especially of the active drug and this is potentially hazardous for the user since dosing becomes unreliable and backup devices [are] not always available.” (’289 patent at 1:49-54 (emphasis added).)

These same specification passages relied on by Defendants undercut their entire argument. While Defendants are correct that the specification contains references to inhalers as “devices,” those references do **not** describe a stand-alone, empty device but instead a device that contains an active drug. *See* Def. Br. at 9-10 (quoting ’289 patent at 1:49-54, 2:20-25, 2:25-31).

Defendants’ citations to the prosecution histories fare no better. Defendants cite to three passages from the prosecution histories of the Asserted Patents that have references to the prior art inhalers and claimed inventions as “devices.” Def. Br. at 10-11. Defendants’ citations to the prosecution histories suffer from the same defect as their citations to the specification—references to an inhaler as a device do not lead to the conclusion that the Inhaler Terms must not include an active drug. For instance, Defendants cite to the same response to a Final Office Action in the ’289 patent file history discussed above and in Teva’s Opening Brief. Def. Br. at 10-11

(citing Def. Ex. 5).⁶ As noted above, in this response, Teva distinguished its claimed inhaler over the examiner's suggestion by highlighting how the claimed inhaler improved the ability of users "to draw air through the inhaler and inhale medicament effectively." Pl. Ex. 8 (File History, U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.) at 6-7. Like the specification, the prosecution history refers to the claimed inhalers containing an active drug (i.e., "medicament"). Defendants' own evidence supports that the common meaning of "inhaler" requires the presence of an active drug.

While Defendants complain that Teva is proposing to read limitations into the claims, that just begs the question of what the Inhaler Terms "plainly and ordinarily mean" in the first place. The technical dictionary cited in Teva's Opening Brief illustrates the common meaning of the claim term. Merriam-Webster's Medical Desk Dictionary (2005) defines (i) "inhaler" as "a device by means of which usu[ally] medicinal material is inhaled" and (ii) "inhalation" as "the action of drawing air into the lungs . . ." and "material (as medication) to be taken in by inhaling." Pl. Ex. 9 (Medical Desk Dictionary (2005)) at 396-97. The common meaning, exemplified by these dictionary definitions, reflects that an inhaler contains medicinal material even if the inhaler is also referred to as a "device." One

⁶ Pl. Ex. 8 is the same portion of the file history of U.S. Patent App. No. 14/103,324 as Def. Ex. 5.

does not exclude the other.

Turning to Defendants' arguments against Teva's proposed construction, the parties' dispute centers on what is the "plain and ordinary" meaning of the Inhaler Terms. Def. Br. at 11-12. Despite arguing that Teva's constructions do not capture the plain and ordinary meaning of the Inhaler Terms, Defendants fail to offer any competing evidence regarding the plain and ordinary meaning of those terms. Def Br. at 9-12. Defendants' argument that Teva's constructions are not supported by evidence of lexicography or disavowal, Def Br. at 11, is a red herring. Lexicography and disavowal describe the circumstances in which a court may depart from a term's plain and ordinary meaning. *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012). Those principles do not help Defendants because as explained above, Teva is not departing from the ordinary meaning. Rather, it is Defendants who are attempting such a departure, by proposing to construe the terms as not requiring an active ingredient. Thus, the onus is on Defendants, not Teva, to offer evidence of lexicography or disavowal. Defendants' Opening Brief offers no such arguments.

Defendants' remaining arguments (at p. 12) focus on the specification, without (again) any analysis of the claim language itself. As noted above and in Teva's Opening Brief, the shared specification repeatedly refers to the claimed inhaler as containing an active drug. To the extent Defendants propose construing

the Inhaler Terms to cover only an empty inhaler, this would result in the exclusion of the preferred embodiment. “Claim interpretations that do not read on the preferred embodiment are ‘rarely, if ever, correct and would require highly persuasive evidentiary support.’” *Nat’l Steel Car, Ltd. v. Can. Pac. Ry., Ltd.*, 357 F.3d 1319, 1336 n.19 (Fed. Cir. 2004) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)).

Defendants’ argument that the specification makes clear that “an active drug” is not a necessary component of an inhaler is based on a misreading of the specification. Defendants first point to the following quote from the “Background of the Invention” in the specification: “[m]etered dose inhalers **can** comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant.” Def Br. at 12 (quoting ’289 patent at 1:27-29 (emphasis added)). Defendants are incorrect that the word “can” in this passage signifies that the active drug is not required in an inhaler. *Id.* What “can” but need not be included in an inhaler is a pressurized canister. As the specification of the Asserted Patents, and the references cited therein, make clear, there are different kinds of inhalers and not all require a pressurized canister. For example, EP-A-1330280 (“EP ’280”), which is incorporated by reference in the specification,⁷ explains: “Existing types of

⁷ The shared specification incorporates by reference EP-A-1330280. *See, e.g.*, ’289 patent at 20:17-19. Through incorporation by reference, the contents of EP ’280 are part of the shared specification for the Asserted Patents. *See Cook Biotech Inc. v.*

medicament dispensing inhalers include pressurized propellant inhalers, aqueous solution inhalers, and dry powdered inhalers.” Pl. Ex. 18 (EP ’280) at 1:14-17; *see id.* at 1:18-54 (describing examples of different types of inhalers disclosed by other references); *see also* ’289 patent at 1:19-23 (“The invention is particularly applicable to metered dose inhalers including dry power medicament inhalers, breath actuated inhalers and manually operated metered dose medicament inhalers.”); ’289 patent at 20:14-17 (“FIGS. 21 and 22 show a preferred embodiment in accordance with the invention of an inhaler 510 for dispensing a dry-powdered medicament in metered doses for patient inhalation.”). Contrary to Defendants’ argument, the context of the specification as a whole demonstrates that the claimed inhalers require the presence of an active drug, even though there are different types of inhalers and not all of them require a pressurized canister.

Defendants’ two other citations to the specification likewise fail to support their argument that an active drug is not required. Def Br. at 12. Defendants rely on two passages from the “Background of the Invention” that acknowledge that a difficulty with inhalers is that the patient cannot see how much “if any” drug or propellant remains in the inhaler (’289 patent at 1:49-54) and that, without an

Acell, Inc., 460 F.3d 1365, 1375 (Fed. Cir. 2006) (“Incorporation by reference provides a method for integrating material from various documents into a host document . . . by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein.” (citation omitted)).

accurate dose counter, the active drug “may run out” without the patient knowing (’289 patent at 2:25-31). These passages do not suggest the claims should be interpreted to cover completely empty inhalers. They do not exemplify an inhaler that never had an active drug in it (i.e., always empty) or even an inhaler in which all active drug was completely expelled (i.e., became fully empty). Indeed, the specification explains that “run out” simply means that the inhaler is not “suitable for use.” *Id.* at 2:25-31. That would occur if the dose of drug were reduced from the labeled amount—the word “empty” is not used at all in the specification. *Compare* Pl. Ex. 6 (03/2012 ProAir® HFA Label) (noting that even when the dose counter reads zero “the canister is not completely empty and will continue to operate”). Instead, these passages highlight the very problems that the claimed inventions solved by accurately counting the doses of the drug administered from an inhaler.

Finally, Defendants disregard the support found in the intrinsic and extrinsic record that the active drug be “capable of being dispensed via the inhaler to the lungs.” Def. Br. at 12. As discussed above, the common meaning of “inhaler”, as exemplified by dictionary definitions, confirms Teva’s proposed construction that the inhaler contains medicinal material that is drawn into the lungs through the inhaler. Pl. Ex. 9 (Medical Desk Dictionary (2005)) at 396-97. The specification further explains that the inhaler dispenses the active drug for inhalation. For

example, the specification explains that “[t]he user can, when readying the inhaler 12 for first use, prime the inhaler by depressing the canister . . . [to] indicat[e] that 200 doses are remaining to be dispensed from the canister 20 and inhaler 12.” ’289 patent at 17:4-10; *see also id.* at 20:14-17 (referring to “dispensing” the “medicament in metered doses for patient inhalation”).

References incorporated by reference and cited in the specification also support Teva’s construction. EP ’280, incorporated by reference in the specification, explains that “[m]etered dose medicament inhalers are well known for dispensing medicament to the lungs of a patient, for treating asthma for example.” Pl. Ex. 18 (EP ’280) at 1:10-14. EP ’227, cited in the specification, contains the same statement. Pl. Ex. 10 (EP ’227) at 1:24-26.

The prosecution history further supports Teva’s proposed construction. As discussed above, Teva distinguished its claimed invention over the examiner’s suggestion by highlighting how the claimed inhaler improved the ability of users “to draw air through the inhaler and inhale medicament effectively.” Pl. Ex. 8 (File History, U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.) at 6-7. This statement demonstrates that the claimed inhaler contains active drug that is effectively inhaled through the inhaler by the user.

* * *

This Court should reject Defendants’ attempts to construe claims explicitly

reciting an inhaler to not be limited to inhalers. Defendants' argument ignores the claims, the specification, and the prosecution history. Instead, the Court should construe the Inhaler Terms, consistent with the common meaning and intrinsic record, as both limiting and as containing an active drug capable of being dispensed via the inhaler to the lungs.

B. The Dose Counter Terms are limiting, and Teva's proposed constructions should be adopted

The disputed Dose Counter Terms (with the numbering from the JCCS) are as follows:

- Term 3: "A dose counter for an inhaler" ('808 patent, claim 1)
- Term 5: "An incremental dose counter for a metered dose inhaler" ('889 patent, claim 1)

Like the Inhaler Terms, the parties dispute (1) whether these preambles are limiting and (2) if so, the proper construction of the disputed term. For each term, the preamble is limiting and the Dose Counter Term should be construed to require the presence of an inhaler.

1. The disputed phrases in the preambles are limiting

The Dose Counter Terms are contained in the same preambles as some of the Inhaler Terms, and the same reasons require interpreting the terms as limiting. Defendants do not raise any additional arguments for why the Court should find these preamble phrases not limiting beyond incorporating by reference the same

reasons they discussed with respect to Inhaler Terms 4 and 6. Def. Br. at 14. Accordingly, for the same reasons discussed above and in Teva's Opening Brief, these preamble phrases are limiting and require construction.

2. The Dose Counter Terms should be construed to require the presence of an inhaler

For both Dose Counter Terms, Teva's proposed construction construes the term "for" to mean "used in connection with," consistent with the plain meaning of that term. Defendants have not proposed a construction that contests that the claimed dose counters of the '808 and '889 patents are "for"—or, require the presence of—an inhaler. Nor could Defendants. The plain meaning of the claim language requires an inhaler to be present. Indeed, the specification does not describe the claimed dose counters being used in connection with anything other than an inhaler. The claimed invention is a dose counter for an inhaler, not a dose counter for an injector pen or any other structure. Without an inhaler, which contains an active drug, there would be no doses to count for the dose counter. Instead, Defendants argue that Teva's proposed construction improperly "require[s] a *specific use* of the dose counter in the claims themselves." Def. Br. at 15 (emphasis added). Defendants' only argument for why Teva's construction should be rejected rests entirely on a misreading of *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).

Contrary to Defendants' assertion, *Union Oil* supports Teva's proposed

construction for the Dose Counter Terms. First, Teva’s construction would not convert a composition claim into a method claim as Defendants argue. Rather, the proposed construction addresses the structure required by the claims. In the context of the Asserted Patents, the problem to be solved concerns the accuracy of a dose counter integrated into an inhaler. The claims should be construed accordingly. *Union Oil*, 208 F.3d at 995-96 (finding “extensive support in the specification” based in part on “the problem that their invention addressed”).

Second, the Federal Circuit’s analysis in *Union Oil* supports adopting Teva’s proposed construction of a dose counter used in connection with an inhaler. As the Federal Circuit explained, the claims at issue in *Union Oil* “specifie[d] fuels for an ‘automotive engine,’ not an aviation engine.” *Id.* at 995. The court thus held that the claims were directed to “cover only a narrow class of fuel compositions, namely only standard automotive gasoline.” *Id.* On this basis, the Federal Circuit affirmed the holding that prior art “aviation and racing fuels that allegedly invalidate the [asserted] claims do not anticipate because they do not contain each and every limitation of the claims.” *Id.* at 996. The Federal Circuit thus limited the claims to the structures for which the gasoline was claimed. The same is true here—the claims require a dose counter for an inhaler. As in *Union Oil*, the structure for which the dose counter is claimed (an inhaler) should be applied as a substantive limitation of the claims.

C. Teva’s proposed constructions for the Canister Terms should be adopted

The parties dispute the plain and ordinary meaning of the two Canister Terms—Term 2 “medicament canister” (’289 patent, claims 1, 2; ’587 patent, claims 1, 2, 12) and Term 7 “canister” (’889 patent, claim 1). Teva’s proposed construction for the Canister Terms—“a canister containing an active drug capable of being dispensed via the inhaler to the lungs”—reflects the plain and ordinary meaning of the terms, and therefore should be adopted. Defendants’ proposal ignores compelling intrinsic evidence to the contrary and runs afoul of black-letter claim construction law.

The crux of Defendants’ argument is that “[t]he plain and ordinary meaning of ‘canister’ cannot depend on its contents.” Def. Br. at 19. Defendants’ argument, however, contravenes well-established law regarding the ordinary meaning of a claim term. Contrary to Defendants’ approach, “[w]e cannot look at the ordinary meaning of the term . . . in a vacuum.” *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005). Rather, “[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art in question at the time of the invention when read in the context of the specification and prosecution history.” *Laryngeal Mask Co. Ltd. v. Ambu*, 618 F.3d 1367, 1370 (Fed. Cir. 2010); *see also Medrad*, 401 F.3d at 1319 (“[W]e must look at the ordinary meaning in the context of the written description and the prosecution

history.”). Defendants disregard that the POSA “is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1313. Defendants’ suggestion that a “claim limitation to a ‘water bottle’ would be directed to the bottle itself, not its contents” exemplifies the issue. Def. Br. at 18. Specifically, Defendants’ narrow focus on the term itself without any context contravenes the requirement that the claim term must be viewed in the context of the entire intrinsic record.⁸

When properly viewing the disputed terms “medicament canister” and “canister” in view of the claims, specification, and prosecution history, it is clear that the plain and ordinary meaning of these terms is not directed just to the canister itself but also its contents. Starting with the claims, Defendants are wrong that the claims do not describe the contents of the canister as containing an active drug. The disputed term “medicament canister” itself evidences that the canister contains a medicament or an active drug. As explained in Teva’s Opening Brief, the parties’ agreed-upon construction of the claim term “main surface of the inner wall” (’289

⁸ Defendants’ construction of the hypothetical “water bottle” claim limitation as limited to the bottle itself falls apart even when improperly assessing it without examining any hypothetical intrinsic record. For instance, Merriam-Webster defines “water bottle” as “a small bottle containing water for drinking.” See *Merriam-Webster.com Dictionary*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/water%20bottle> (last visited Sep. 27, 2024). This definition of “water bottle” *is* directed to the bottle *and* its contents (water).

patent, claim 1; '587 patent, claims 1, 12) specifies that the medicament canister will “expel medicament.” D.E. 111-1 (JCCS) at 3-4. Defendants’ agreement that the medicament canister will “expel medicament” requires that the canister contains a medicament.

The surrounding claim language confirms that the canister must contain an active drug that is capable of being dispensed via the inhaler to the lungs. *Phillips*, 415 F.3d at 1314 (“[T]he context in which a term is used in the asserted claim can be highly instructive.”). As explained above and in Teva’s Opening Brief, each of these claims is limited to an “inhaler.” As such, the active drug in the canister likewise must be limited to being capable of being dispensed via that inhaler. Other claim language supports the same. For instance, the relevant independent claims of the '289 and '587 patents require a medicament canister that has a “canister fire stem,” which fires active drug from the canister. Teva’s construction reflects the plain meaning of the claim language.

Contrary to Defendants’ assertions, the specification also describes that the contents of the canister contain an active drug capable of being dispensed via the inhaler to the lungs. For example, the specification states that the “the valve stem block 40 has a passageway 42 leading to a nozzle 44 for directing *the contents of the canister 20, namely active drug and propellant*, towards an air outlet 46 of the inhaler main body 12.” '289 patent at 12:26-29 (emphasis added). The specification

also describes that a patient can “prime the inhaler” to indicate that “200 doses are remaining to be dispensed from the canister 20 and inhaler 12.” *Id.* at 17:4-10. These passages demonstrate that the contents of the canister—an active drug—are dispensed from the inhaler.

Defendants put forward the same arguments for the Canister Terms as they did with the Inhaler Terms, relying on the same citations to the specification. Def Br. at 19. These arguments fail for the Canister Terms for the same reasons discussed above with respect to the Inhaler Terms in Section II.A.2.

References incorporated by reference and cited in the specification further support Teva’s construction. These references provide additional examples of the active drug in the canister being capable of being dispensed via the inhaler to the lungs. *See* Pl. Ex. 18 (EP ’280) at 1:10-14 (“Metered dose medicament inhalers are well known for dispensing medicament to the lungs of a patient, for treating asthma for example.”); *see also* Pl. Ex. 10 (EP ’227) at 1:24-26. Similarly, cited reference WO ’552 states that “[t]he medicament may be any medicament that is suitable to be delivered to a patient via a metered-dose inhaler.” Pl. Ex. 12 (WO ’552) at 13:28-29. WO ’552 then lists examples of such medicaments as follows:

In particular medicaments for the treatment of a wide variety of respiratory disorders are delivered in this manner including anti-allergic agents (e.g. cromoglycate, ketotifen and nedocromil), anti-inflammatory steroids (e.g. beclomethasone dipropionate, fluticasone, budesonide, flunisolide, ciclesonide, triamcinolone acetonide and mometasone furoate); ***bronchodilators such as:*** β 2-agonists (e.g.

fenoterol, formoterol, pirbuterol, reproterol, **salbutamol**, salmeterol and terbutaline), non-selective β -stimulants (e.g. isoprenaline), and xanthine bronchodilators (e.g. theophylline, aminophylline and choline theophyllinate); and anticholinergic agents (e.g. ipratropium bromide, oxitropium bromide and tiotropium).

Id. at 13:29-14:6 (emphasis added). This list includes a variety of medicaments that can be dispensed via an inhaler, including the drug “salbutamol,” which is another name for the drug albuterol. *See* Pl. Ex. 6 (03/2012 ProAir® HFA Label) (“Albuterol sulfate is the official generic name in the United States, and salbutamol sulfate is the World Health Organization recommended generic name.”).

Finally, the prosecution history likewise supports Teva’s proposed construction. As discussed above, Teva distinguished its claimed invention over the examiner’s suggestion by emphasizing how the claimed inhaler improved the ability of users “to draw air through the inhaler and inhale medicament effectively.” Pl. Ex. 8 (File History, U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.) at 6-7. The prosecution history demonstrates that the active drug in the canister must be capable of being dispensed via the inhaler to the lungs.

* * *

Defendants’ proposal and arguments improperly assess the Canister Terms in a vacuum, divorced from the intrinsic record. Teva’s proposed construction, on the other hand, reflects the plain and ordinary meaning of these terms. In view of the intrinsic record as a whole, a POSA would understand the plain and ordinary

meaning of the Canister Terms to mean a canister containing an active drug capable of being dispensed via the inhaler to the lungs.

III. CONCLUSION

For the foregoing reasons and those expressed in its Opening Brief, Teva respectfully requests that the Court adopt its proposed constructions for each of the disputed terms and reject Defendants' proposals.

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